

5. General Monograph Considerations and Labeling

5.A. Plaque claims should be considered cosmetic as long as they are qualified as cosmetic within the totality of the label.

The Plaque Subcommittee proposed that "any reference to the control of dental plaque or its equivalents, with or without qualifications, should be interpreted as a drug claim."⁵⁸ They also proposed that "antiplaque claims should not stand alone" in that the product must also demonstrate a clinically significant effect on gingivitis.

Procter & Gamble disagrees with the Subcommittee's recommendation that all plaque claims should be considered drug claims and urge the Agency to reject the Subcommittee's advice and to recognize that a product with properly qualified plaque claims can be a cosmetic and not a drug. It is our recommendation that an antiplaque effect is a cosmetic, and only a cosmetic, if its antiplaque claims and labeling pertain only to cosmetic benefits and no inference is made to associate the antiplaque benefit with a therapeutic outcome. To determine whether the plaque claim is drug or cosmetic, one must read the product's full labeling in order to determine the intended use of the product. This will clearly determine whether the plaque claim is one that is therapeutic in nature, or whether it is cosmetic.

The list of cosmetic purposes in the statutory definition of a "cosmetic" includes not only "altering the appearance," but also "cleansing, beautifying, [and] promoting attractiveness." 21 U.S.C. 321(i). The inclusion of "cleansing" leaves no doubt that an antiplaque product has a cosmetic purpose if it is used to promote "oral hygiene" or to "clean" or "freshen" the mouth or teeth. Cosmetic benefits from oral care products also include cleaner and whiter teeth, less tartar formation, cleaner feeling mouth, smoother feeling teeth and fresher breath all of which culminate to provide overall

⁵⁸ Federal Register. 68 (103): May 29, 2003 at page 32239.

mouth refreshment and improved dental appearance. As long as these types of cosmetic benefit qualifiers are linked in the labeling to the plaque effects, then the plaque claim should be permitted without incurring presumption of therapeutic benefits.

5.A.1. FDA Recognizes That Oral Care Products, Including Mouthwashes And Dentifrices, Are Cosmetics And Not Drugs If They Are Intended To Be Used For Cosmetic Purposes Only

The FDA regulations identifying “cosmetic product categories” recognize that “dentifrices,” “mouthwashes and breath fresheners,” and “other oral hygiene products” may come within the definition of a cosmetic. 21 C.F.R. § 720.4I(9). Indeed, an oral hygiene product is ordinarily classified as a cosmetic if no therapeutic claims are made for it. For example, prior to the introduction of fluoride, all toothpastes in the United States were cosmetics and not drugs because they were sold solely for the purpose of cleaning (or whitening) teeth and freshening breath. Non-fluoride dentifrices continue to be regulated exclusively as cosmetics in the absence of therapeutic claims. Similarly, FDA has classified certain mouthwashes as cosmetics for many years because they claim only to freshen breath and reduce malodor.^{59/}

FDA regulates non-fluoride dentifrices and mouthwashes as cosmetics when they are promoted only for cosmetic uses, even though their ability to abrade or rinse away plaque and food debris may have disease-preventive effects. Similarly, the Agency has confirmed that although antimicrobial soaps may reduce bacteria on the skin that cause disease, “[s]oap products that contain antimicrobial ingredients will be considered ‘cosmetics,’ and not ‘drugs,’ if only deodorant claims (or other cosmetic

^{59/} FDA's OTC advisory panel on Oral Health Care Drugs affirmed that mouthwashes used for cleansing and deodorizing the mouth are cosmetics in the absence of therapeutic claims. 47 Fed. Reg. 22760, 22778-79, 22,843-44 (May 25, 1982).

claims) are made for the products.”⁶⁰ FDA also treats skin moisturizers labeled for cosmetic uses as cosmetics, despite the fact that they may prevent skin cracking, which can lead to infection. *See* 21 C.F.R. § 720.4I(12)(vi); “*Sudden Change*,” 409 F.2d at 741-42 n.10.

These examples confirm that a cosmetic product is not also a drug simply because it has collateral therapeutic benefits. This is further demonstrated in a recent letter from FDA Chief Counsel Daniel E. Troy⁶¹ determining that an implanted identification device that has no medical purpose is not a medical device under the FD&C Act:

“It is well settled that intended use is determined with reference to marketing claims.

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a foreseeable effect on the structure or function of the body does not establish an intended use.

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Foreseeability by the manufacturer does not suffice to establish intended use. Rather, there must be ‘objective intent’ in the form of marketing claims.”

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This recent statement reiterating the Agency’s interpretation of “intended use” defines the criteria for which to determine the statutory definition of a product and further supports our recommendation that plaque-related statements in labeling when appropriately qualified can be either therapeutic or cosmetic. This qualification is based on the totality of the label and labeling.

⁶⁰ Federal Register: 56(33644), July 22, 1991.

⁶¹ Letter from FDA Chief Counsel Daniel E. Troy to Jeffrey N. Gibbs (October 17, 2002).

The Joint Oral Care Task Group of the Consumer Healthcare Products Association (CHPA) and the Cosmetic, Toiletry, and Fragrance Association (CTFA), of which Procter & Gamble is a member, provides substantial support for the recommendation that qualified plaque claims are cosmetic. Their submission provides an extensive review of the regulatory and legal basis that fully supports the premise that qualified antiplaque claims should be regarded as cosmetic if the intended use of the plaque claim is for a cosmetic benefit. We fully support this position. We urge the Agency to carefully consider the discussion by the Task Group on this important matter and independently consider the regulatory status of antiplaque products and determine that they are cosmetics, and not drugs, if their antiplaque claims are qualified by statements regarding cosmetic benefits, and no mention or inference is made of therapeutic plaque uses.

5.A.2. Plaque Reduction is not Sufficient to Establish a Therapeutic Effect, so Plaque Claims Should Not be Limited to Drug Status. Antiplaque Representations Qualified By Reference To Cosmetic Benefits Are Cosmetic Claims, Not Drug Claims

Representations in labeling regarding the removal or reduction of plaque are often related, through qualifying statements, to the cosmetic outcomes discussed above. Procter & Gamble is in full and complete agreement with the Oral Care Task Group rationale that plaque-related statements qualified by reference to cosmetic benefits are cosmetic claims exclusively.

The Plaque Subcommittee in its report linked the therapeutic effects of antiplaque products with reduction of the disease gingivitis.

“The Subcommittee accepts that gingivitis is associated with an accumulation of plaque along the gingival margin but is unaware of

*any evidence that shows that there is a close correlation between the amount of plaque and the induction of gingivitis, as can be assessed using present day methods. It should be noted that the relationship between the quantity of plaque present and the degree of gingivitis is sufficiently complex such that reductions in plaque mass alone are inadequate to conclude that a therapeutic effect on gingivitis could be expected. Therefore, gingivitis reductions must be measured directly."*⁶²

An antiplaque claim is not inexorably a drug claim, because plaque itself may not have an effect on the disease, gingivitis. Plaque is, rather, a phenomenon that occurs nearly universally in even the healthiest individuals and has both disease-related and cosmetic consequences. Plaque buildup can lead to the development of gingivitis and periodontal disease, but as indicated by the Plaque Subcommittee above, it does not invariably do so. On the contrary, "mouths can frequently be observed in which plaque is not associated with disease."^{63/} Scientific studies reviewed by the Plaque Subcommittee have provided evidence that some types of plaque are not related to gingivitis and other forms of gum disease at all.^{64/}

The undeniable cosmetic consequences of plaque and the strong cosmetic associations of plaque removal products would make it unreasonable as a factual matter for FDA to

⁶² Federal Register. 68(103) at page 32237. May 29, 2003.

^{63/} Bowen, *The Prevention or Control of Dental Plaque*, in *Dental Plaque* 283 (W. McHugh ed. 1970). See also Bowen, *Future Directions for Dental Plaque Control Measures and Oral Hygiene Practices: Perspective II*, in *Dental Plaque Control Measures and Oral Hygiene Practices* 306 (H. Löe & D. Kleinman, ed. 1986)("[T]here is no simple, direct relationship between the accumulation of dental plaque and the onset of oral disease."); Ramfjord et al., *Oral Hygiene and Maintenance of Periodontal Support*, 53 J. Periodontal 26 ("In many children and some adults one may find definite plaque on the teeth without clinical evidence of gingivitis.").

^{64/} M. Pader, *Oral Hygiene Products and Practice* 69 (1988) and Federal Register 68(103) at page 32236. May 29, 2003.

conclude that a claim of plaque removal can *only* be a disease prevention indication. The cosmetic or drug status of an antiplaque product must be determined primarily by qualifications of the antiplaque claim as reflected in the totality of the product labeling and advertising.

In a parallel situation, FDA has taken the position that the phrase “kills germs” is a cosmetic claim, and not a drug claim, if it is linked to a cosmetic benefit, such as deodorization. In 1973, FDA’s Chief Counsel explained the Agency’s position on this matter to the Oral Cavity Panel during its consideration of antimicrobial mouthwashes:

The claim “kills germs that cause odor” would be considered a cosmetic claim; the claim “kills germs that can cause disease” would be considered a drug claim.^{65/}

Fifteen years later, Dr. William Gilbertson, longtime Director of the FDA OTC Drug Review, reiterated this FDA policy. He stated that the claim “*kills germs that cause mouth odor*” would be a cosmetic claim, “since the end result is a cosmetic one.”^{66/}

This approach guided the Agency’s deliberations concerning antiperspirant drug products. The Antiperspirant Panel recognized that antimicrobial deodorants are cosmetics and not drugs.⁶⁷ In the tentative final monograph, FDA concurred with the Panel’s decision not to review deodorant claims for antimicrobial products.⁶⁸

^{65/} Minutes of the Third Meeting of the Panel for Review of OTC Oral Cavity Drug Products 2 (July 13-14, 1973).

^{66/} William Gilbertson, *FDA OTC Drug Standards Versus Cosmetic Standards*, 21 Drug Info. J. 379, 382 (1987).

⁶⁷ Federal Register: 43(46694, 46712), October 10, 1978.

⁶⁸ Federal Register: 47(9492, 9494), August 20, 1982.

The Tentative Final Monograph for OTC dandruff products, in which the Agency explained that: *“the mere use of the word “dandruff” does not automatically render a shampoo or other hair care product subject to regulation as a drug. . . . When the use of the term “dandruff” deals only with appearance and not with the treatment or prevention of the underlying disease condition, as in the context that a product removes loose flakes or cleans the hair of dandruff flakes and scales, the product is cosmetic in nature.”*⁶⁹

The Agency has continued to adhere to its policy that antimicrobial claims, when expressly linked to cosmetic benefits, are cosmetic claims and not drug claims. For instance, in a 1990 letter to a company proposing to market a dentifrice product claiming simply to “fight bacteria,” Richard J. Chastonay, Director of the Division of Drug Labeling Compliance, expressed reservations about the company’s contention that this was a cosmetic claim. His reservations were based on the fact that the label and promotional material said nothing to suggest that the antimicrobial action was intended to fight bad breath. *“Without any qualification on the use of the antimicrobial ingredient, we can only conclude . . . that the antimicrobial activity is intended for drug use.”*^{70/} By obvious implication, a properly qualified antimicrobial claim, such as “fights bacteria to control bad breath,” would have been treated by the Agency as a cosmetic claim. FDA has therefore maintained the position that if a product claims to achieve an effect (“kills germs,” “removes plaque”) that has both therapeutic and cosmetic benefits, its regulatory classification depends on how the claim is qualified.

⁶⁹ Federal Register: 51(27346-27348),

^{70/} Letter from Richard J. Chastonay (FDA) to William E. Cooley (Procter & Gamble), December 6, 1990, at 2(emphasis added).